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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/576,816	04/24/2006	Florence Henry	C 2874 PCT/US	9093
23657	7590	03/14/2011	EXAMINER	
FOX ROTHSCHILD LLP			MI, QIUWEN	
997 Lenox Drive, Bldg. #3			ART UNIT	
Lawrenceville, NJ 08648			PAPER NUMBER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ipdocket@foxrothschild.com

Office Action Summary	Application No. 10/576,816	Applicant(s) HENRY ET AL.	
	Examiner QIUWEN MI	Art Unit 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 February 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-17, 19 and 21-33 is/are pending in the application.
- 4a) Of the above claim(s) 22-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12-17, 19, 21, 32 and 33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date. _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's amendment in the reply filed on 2/18/2011 is acknowledged, with the newly added claim 33. Claims 1-11, 18, and 20 have been cancelled. Claims 12-17, 19, and 21-33 are pending. Claims 22-31 are withdrawn. **Claims 12-17, 19, 21, 32 and 33 are examined on the merits.**

Any rejection that is not reiterated is hereby withdrawn.

Please disregard reference Wang et al mentioned in the last office action, that reference was not recited in the rejections.

Claim Rejections –35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 14-17, 19, 21, and 32 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Chernane et al (Chernane et al, Phenolic composition of the pulp of fruits of argan (*Argania spinosa*) in relation to morphological characteristics Composition phenolique de la pulpe des fruits d'arganier (*Argania spinosa* L. Skeels) et relation avec leurs caracteristiques

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morphologiques, *Agrochimica*, (1999) Vol. 43, No. 3/4, pp. 137-150), in view of Basu-Modak et al (Basu-Modak et al, Epicatechin and its methylated metabolite attenuate UVA-induced oxidative damage to human skin fibroblasts, *Free radical biology & medicine*, (2003 Oct 15) Vol. 35, No. 8, pp. 910-21), and further in view of Katiyar et al (Katiyar et al, Green tea polyphenolic antioxidants and skin photoprotection (review), *International Journal of Oncology* 18: 1307-1313, 2001).

This rejection is maintained for reasons of record set forth in the Office Action mailed out on 11/19/2010, repeated below, slightly altered to take into consideration Applicant's amendment filed on 9/24/07. 2/18/2011 Applicants' arguments filed have been fully considered but they are not deemed to be persuasive.

Chernane et al teach phenolic compounds of argan (*Argania spinosa*) fruit pulp (thus the limitation of claim 19 is met)- collected from a stand near Essaouira, Morocco - were characterized. The amount of phenolic compounds in the pulp could be used to distinguish between four morphological forms of fruit: spherical, oval, oval-apiculated and spindle-shaped [fusiform]. The spindle-shaped fruits had a higher phenolic content (7.2 mg/g fresh weight (FW) pulp), compared to the spherical and oval forms, which contained 4.8 and 5.02 mg/g FW, respectively. The oval-apiculated form appeared to have an intermediate amount of phenolic compounds (5.8 mg/g FW). The analysis of phenolic extracts by HPLC showed a quantitative difference of some phenolic compounds, particularly (-)-epicatechin, other unidentified flavans and quercetin derivatives. A positive correlation between total phenol content and phenotypic characters was established (see Abstract) (full translation is attached). Chernane et al also teach MF of the pulp contains 1547-2492 $\mu\text{g/g}$ (thus about 1.5 mg/g-2.5 mg/g of the fruit extract,

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which is about 0.15-0.25% of epicatechin among fruit extract, thus falls within the claimed range of 0.03-5%, 0.01-25%, and 0.03-0.6%) depending up the shape of the fruits (page 15, Table 4).

Chernane et al further teach ripe argan fruit contains catechin.

Chernane et al do not teach a method of treating skin damage by UV-A and/or UV-B by applying to skin a solvent extract from the pulp of *Argania spinosa* fruit and at least one dermatopharmaceutical auxiliary and/or additive; neither do Chernane et al teach the claimed amount of auxiliaries and additives.

Basu-Modak et al teach the ultraviolet A component of sunlight causes both acute and chronic damage to human skin. In this study the potential of epicatechin, an abundant dietary flavanol, and 3'-O-methyl epicatechin, one of its major in vivo metabolites, to protect against UVA-induced damage was examined using cultured human skin fibroblasts as an in vitro model. The results obtained clearly show that both epicatechin and its metabolite protect these fibroblasts against UVA damage and cell death (see Abstract).

Katiyar et al teach chronic exposure of solar ultraviolet (UV) radiation to human skin is the primary cause for the vast majority of cutaneous malignancies. UV radiation, particularly UVB (290-320 nm) within the solar spectrum can act as both tumor initiator and tumor promoter by damaging critical cellular macromolecules such as DNA, proteins and lipids (page 1307, 2nd column, 2nd paragraph). Katiyar et al teach we also observed that topical treatment of GTP (polyphenols of green tea) or EGCG (3 mg/2.5 cm²) before UVB exposure to human skin significantly reduced UVB-induced erythema development (page 1309, 1st column, 1st paragraph). The polyphenols present in green tea are known as epicatechins or epicatechin derivatives. The major epicatechins found in green tea are, (-) epicatechin (EC), and (-)

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epigallocatechin-3-gallate (ECG), (-) epigallocatechin (EGC), and (-) epigallocatechin-3-gallate (EGCG) (thus an antioxidant) (page 1308, 2nd column, 2nd paragraph).

It would also have been prima facie obvious for one of ordinary skill in the art at the time the invention was made to apply extract from pulp of *Argania spinosa* fruit containing epicatechin to skin to treat skin damage caused by UV-A since Basu-Modak et al teach epicatechin protects against UVA-induced skin damage. It is noted that the pulp fruit extract of *Argania spinosa* contains 0.15-0.25% epicatechin, which falls with the claimed range of 0.03-5%, 0.01-25%, and 0.03-0.6%.

It would also have been prima facie obvious for one of ordinary skill in the art at the time the invention was made to apply extract from pulp of *Argania spinosa* fruit containing epicatechin to skin to treat skin damage caused by UV radiation since Katiyar et al teach topical application of GTP containing major epicatechins for the treatment of UVB-induced erythema. It would also have been prima facie obvious for one of ordinary skill in the art at the time the invention was made to use a carrier such as a lotion or a cream by including a dermatopharmaceutical auxiliary emulsifier thus (the limitation of claim 32 (b) is met). It would also have been prima facie obvious for one of ordinary skill in the art at the time the invention was made to include a preservative in the topical composition.

Regarding the limitation to the claimed amount of the auxiliaries or additive in the composition, the result-effective adjustment in conventional working parameters is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan. For instance, the pulp extract of *Argania spinosa* could be further diluted with water, or being administered through a carrier such as a lotion or a cream.

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It has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. The differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be *prima facie* obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%.); see also *Peterson*, 315 F.3d at 1330, 65 USPQ2d at 1382 (“The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages.”); *In re Hoeschele*, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969) (Claimed elastomeric polyurethanes which fell within the broad scope of the references were held to be unpatentable thereover because, among other reasons, there was no evidence of the criticality of the claimed ranges of molecular weight or molar proportions.). For more recent cases applying this principle, see *Merck & Co. Inc. v. Biocraft Laboratories Inc.*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989); *In re Kulling*, 897 F.2d 1147, 14 USPQ2d 1056 (Fed. Cir. 1990); and *In re Geisler*, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997). see MPEP § 2144.05 part II A. Although the prior

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art did not specifically disclose the claimed amount of auxiliaries and additives, it would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable and optimal concentrations of components, which would have been routinely determined and optimized in the pharmaceutical art.

From the teachings of the references, it is apparent that one of the ordinary skills in the art would have had a reasonable expectation of success in producing the claimed invention.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

Claims 12-17, 19-21, and 32 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Chernane et al, Basu-Modak et al and Katiyar et al as applied to claims 14-17, 19, 21, and 32 above, and further in view of Charrouf et al (Triterpenes and sterols isolated from the pulp of *Argania spinosa* (L.), Sapotaceae, *Plantes Medicinales et Phytotherapie* 25 (203), 112-117, 1991) (see full translation attached).

This rejection is maintained for reasons of record set forth in the Office Action mailed out on 11/19/2010, repeated below, slightly altered to take into consideration Applicant's amendment filed on 9/24/07. 2/18/2011 Applicants' arguments filed have been fully considered but they are not deemed to be persuasive.

The teachings of Chernane et al, Basu-Modak et al and Katiyar et al are set forth above and applied as before.

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The combination of Chernane et al, Basu-Modak et al and Katiyar et al do not specifically teach the extract comprises a non-saponifiable fraction or a triterpene-fraction.

As evidenced by Charrouf et al, tripterpenic alcohols and sterols were isolated from the unsaponifiable fraction of the pulp's lipidic extract of *Argania spinosa*, and these compounds are lupeol, beta and alpha-amyrines, etc (see page 1, Abstract). Charrouf et al also that Argan tree (the same as *Argania spinosa*) produces a fruit called "Argan", which is formed of a fleshy part or pulp and a very hard core containing an oleaginous seed.

Claim 33 is newly rejected under 35 U.S.C. 103(a) as being unpatentable over Chernane et al, Basu-Modak et al and Katiyar et al as applied to claims 14-17, 19, 21, and 32 above, and further in view of Wang et al (Wang et al, Extraction of tea polyphenol, Guangzhou Huagong (2001), 29(4), 27-29).

This is a new rejection necessitated by the Applicant's amendment filed on 10/9/07.

The teachings of Chernane et al, Basu-Modak et al and Katiyar et al are set forth above and applied as before.

The combination of Chernane et al, Basu-Modak et al and Katiyar et al do not specifically teach a supercritical carbon dioxide extract.

Wang et al teach tea polyphenol was extracted with supercritical carbon dioxide fluid. The effects of extraction pressure, temperature and time on the extraction rate of tea polyphenol were studied. The best extraction conditions were obtained (see Abstract) (full translation is attached).

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It would also have been prima facie obvious for one of ordinary skill in the art at the time the invention was made to use supercritical carbon dioxide to extract polyphenols from argan fruit since Wang et al teach extracting polyphenols from tea. Therefore, one of the ordinary skills in the art would have been motivated to extract polyphenols from argan fruit. It is well known in the art that alcoholic extraction and supercritical carbon dioxide extraction are used interchangeably in the art.

From the teachings of the references, it is apparent that one of the ordinary skills in the art would have had a reasonable expectation of success in producing the claimed invention.

Thus, the invention as a whole is prima facie obvious over the references, especially in the absence of evidence to the contrary.

Conclusion

No claim is allowed.

Applicant's amendment in the reply filed on 4/15/08 is acknowledged, with the cancellation of Claims 1-15; and the additional newly added Claims 16-36. Claims 16-36 are pending. Any rejection that is not reiterated is hereby withdrawn.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Qiuwen Mi whose telephone number is 571-272-5984. The examiner can normally be reached on 8 to 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Qiuwen Mi/

Primary Examiner, Art Unit 1655